



ISO 13485:2016\*

## 医疗器材外壳材料

Advanced Resins for Medical Device Housing Applications

现今的医疗设备外壳应用，需要材料具先进性，包括能延长产品使用寿命；如产品带电，则须符合相应的 UL 等级。除此之外，材料还需带来优秀的外观。医疗级的 EMERGE™ 高性能树脂汇聚各种聚合物和添加剂，以满足种种关键性能需求。其技术资讯详见下表：

Medical equipment housing in use today demands materials that deliver a unique combination of advanced properties, including toughness for enhanced product life, compliance with UL standards for powered devices, and an appealing visual appearance. Medical grades of EMERGE™ Advanced Resins from Trinseo bring together selected polymers and additives that meet these most critical needs.

牌号 Grade	特性 Features	熔融率 MFR (g/10mins, ASTM D1238)	弯曲模量 Flexural Modulus (MPa ASTM D790)	维卡软化温度 Vicat Softening Temperature (ASTM D1525)	UL 等级 UL Rating	生物相容性 Biocompatibility
EMERGE™ PC/ABS 7100 MED	•高流动 High flow	25 (260°C/5.0kg)	2430 MPa	133°C	HB@1.0mm	ISO 10993
EMERGE™ PC/ABS 7700	•阻燃 Ignition resistant •抗紫外线 UV resistant	11 (230°C/3.8kg)	2690 MPa	104°C	V0@1.5mm 5VB@2.0mm 5VA@2.5mm	ISO 10993 Part 5 & 10
EMERGE™ PC/ABS 7710	•阻燃 Ignition resistant	11 (230°C/3.8kg)	2690 MPa	104°C	V0@1.5mm 5VB@2.0mm 5VA@2.5mm	

\*盛禧奥的医疗制造设施及全球其他相关部门，均通过 ISO 13485 最新的 2016 版本认证，更具严谨的风险管理和工艺验证。Trinseo's medical manufacturing facilities and related global functions are ISO 13485 certified with the latest 2016 version that places a greater emphasis on risk management and process validation.



# 致力满足您的需求 Focused on Meeting Your Needs

EMERGE™ PC/ABS 7100 MED 及 7700 高性能树脂，是专门为医疗设备外壳应用而设。EMERGE™ PC/ABS 7100 MED 高性能树脂是高流动树脂，良好外观适用于一般医疗设备外壳。如医疗设备是带电装置，阻燃性能相对较为关键，则可选择具阻燃及抗紫外线的 EMERGE™ PC/ABS 7700 高性能树脂。如不需抗紫外线性能，则可选用 EMERGE™ PC/ABS 7710 高性能树脂。

EMERGE™ PC/ABS 7100 MED and 7700 Advanced Resins have been specially designed for medical device housing. EMERGE™ PC/ABS 7100 MED are high-flow resins featuring a balanced property that's suitable for regular medical device housing. For housing materials used for powered equipment in which flammability is crucial, EMERGE™ PC/ABS 7700 is the material of choice as it offers the ignition and UV resistances required. EMERGE™ PC/ABS 7710 is the preferred selection if no UV resistance is needed.

## 独特优势 Distinctive Advantages

### 提供订制颜色 Custom Colors Available



- 原色及订制颜色以供选择  
Natural and custom colors available.
- 盛禧奥提供订制预着色树脂，所有预着色树脂均符合 ISO 10993 标准  
Trinseo offers customized pre-color resins. All pre-color resins are compliant with ISO 10993.

### 阻燃 Ignition Resistance



#### EMERGE™ PC/ABS 7700, 7710

- UL 等级为 V0@1.5mm, 5VB@2.0mm, 5VA@2.5mm  
UL rating at V0@1.5mm, 5VB@2.0mm, 5VA@2.5mm.

### 成品美观 Pleasing Aesthetics



- 其紫外线稳定性能有助减少成品随时间变色  
UV stabilized with minimized color shift over time.

### 耐用 Durability



- 极佳的韧性及冲击强度  
Outstanding toughness and impact strength.
- 提供日常在不同环境下使用所需的耐用度  
Offers the durability required for daily use in a variety of environments.

### 生物相容性 Biocompatibility



#### EMERGE™ PC/ABS

- 7100 MED 符合 ISO 10993 标准  
7700 & 7710 符合 ISO 10993 Part 5 & 10 标准  
7100 MED - ISO 10993 compliant,  
7700 & 7710 - ISO 10993 Part 5 & 10 compliant.

### 加工容易 Easy Processing



- 优良的热稳定性  
Good thermal stability.
- 于高温加工时冲击强度保持不变  
Impact strength maintains at high processing temperatures.



# 应用推介

## Recommended Applications

EMERGE™ PC/ABS 7100 MED 树脂建议使用于一般医疗设备外壳  
 EMERGE™ PC/ABS 7100 MED Advanced Resins are recommended for general medical device housing applications



EMERGE™ PC/ABS 7700 及 7710 树脂建议使用于带电医疗设备外壳  
 EMERGE™ PC/ABS 7700 and 7710 Advanced Resins are recommended for powered medical device housing applications



# 法规支援及品控程序

## Regulatory Support and Quality Processes

我们理解医疗合规的重要性，盛禧奥已设立了完善的内部流程，确保行业严格的法规得以遵守。我们的法规专家服务全球；我们非常重视合规性，并努力保持领先地位。

盛禧奥以严格的质控指引、监控条件、及经过验证的各种流程来生产医疗等级树脂，并关注供应的稳定性。我们致力为客户提供一致、可信赖和可持续的产品。为了满足正规要求和文件需要，我们改善了管理流程，包括：

- 锁定配方
- 变更通知 (NOC)
- 批次追溯性
- 长期记录和样品保存期

我们的目标是给客户一站式的服务和支援。

We understand that medical regulatory compliance is critical for all manufacturers. Trinseo has developed internal processes to ensure the industry's stringent guidelines are met. As such, our regulatory expertise is recognized and appreciated globally, and we place a strong emphasis on maintaining this leadership position.

Trinseo produces its medical grade resins under stringent quality guidelines, controlled conditions and validated processes. Our multiple resin sources provide an assurance of supply. We are committed to providing product consistently, predictably and sustainably. To accommodate formal requirements and the need for documentation, we offer a Management of Change process that includes:

- Formulation Lock
- Notification of Change (NOC)
- Lot Traceability
- Extended Record and Sample Retention

Our goal is to provide end-to-end support to our customers.





盛禧奥 (Trinseo) 和其附属公司在文件印刷方面均秉承责任关怀® 和可可持续发展的原则。为保护环境, 只印刷少量资料, 并尽可能使用含有可回收 / 再生纤维的纸张, 并尽可能使 100% 豆制品油墨印制。

The principles of Responsible Care® and Sustainable Development influence the production of printed literature for Trinseo S.A. and its affiliated companies. As a contribution towards the protection of our environments, Trinseo's printed literature is produced in small quantities and on paper containing recovered/post-consumer fiber and using 100 percent soy-based ink whenever possible.

#### 产品监管 PRODUCT STEWARDSHIP

盛禧奥及其附属公司拥有一个基本原则, 就是关怀所有制造、分销和使用其产品的人员以及我们生活的环境。这是我们的产品监管原则的基础, 我们根据监管原则评估我们产品的安全、卫生和对环境的影响, 然后采取适当措施来保护我们的员工、公共卫生和环境。我们产品监管的成功取决于与盛禧奥产品有关的每个人 - 从每件产品的构思和研究开始到制造、使用、销售、处置以至循环再生。

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products - from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

#### 客户注意事项 CUSTOMER NOTICE

客户有责任从健康和环境保护出发, 全面检查其生产过程以及对盛禧奥产品的应用, 以保证盛禧奥的产品不会被以其不适合的方式使用。盛禧奥人员将回答您的问题并提供合理的技术支持。客户在使用盛禧奥产品之前, 应该查阅盛禧奥的产品文献, 包括安全数据表。目前, 安全数据表可从盛禧奥获得。

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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For additional information not covered by the content of this document or to ensure you have the latest version of this document available, please refer to the Customer Information Group contact information on our website at [www.trinseo.com/contact/](http://www.trinseo.com/contact/).

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